

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Emerson, S.U. et al. Group Art Unit: 1643
Serial No. : 08/840,316 Examiner: Zeman, M.
Filed : April 11, 1997
For : RECOMBINANT PROTEINS OF A PAKISTANI STRAIN OF
HEPATITIS E AND THEIR USE IN DIAGNOSTIC METHODS
AND VACCINES

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.132

We, Robert H. Purcell, M.D., Suzanne U. Emerson, Ph.D., Robin Robinson,
Ph.D. and Sergei A. Tsarev, Ph.D. state:

1. We have read and understood application 08/840,316, including the
claims.
2. We are the named co-inventors of the above-mentioned patent application.
3. We, together with T.S. Tsarev, S. Govindarajan, M. Shapiro, J.L. Gerin
and A.E. Gorbalenya co-authored the article entitled "Prospects for Prevention of Hepatitis E"
which was contained in a book entitled "Enterically Transmitted Hepatitis Viruses" which
published July 31, 1996.

4. The disclosure in the article does not correspond to the oral presentation at the October 16-17, 1995 in Paris, France. In particular, the disclosure of a DNA encoding amino acids 112-609 of the HEV ORF2 protein was first made in the published article.

5. While the contributions of T.S. Tsarev, S. Govindarajan, M. Shapiro, J.L. Gerin and A.E. Gorbalenya to the subject matter of the article were such that authorship was warranted, their work did not make an inventive contribution to the subject matter claimed in application 08/840,316.

6. We hereby declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under Section 1001 to Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 3/16/99

By: Robert H. Purcell
Robert H. Purcell, M.D.

Dated: 3/16/99

By: Suzanne U. Emerson
Suzanne U. Emerson, Ph.D.

Dated: 3-16-99

By: Robin A. Robinson
Robin Robinson, Ph.D.

Dated: 3-15-99

By: Sergei A. Tsarev
Sergei A. Tsarev, Ph.D.